

FDA Plasma Standards Workshop

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Bethesda, MD

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Use of Plasma

Type	F VIII, vWF	IVIG, Albumin
Source Plasma	X	X
Recovered < 24 hr	X	X
Recovered < 120 hr		X

Plasma Specifications

Type	Separation	Freeze	Store	Ship	Expiry
SP	Apheresis	= -30 C ¹ = -20 C ²	= -20 C	= -20 C	10 yr
RP <24 hr	Whole blood/spin	= -18 C	= -18 C	= -20 C	3 yr
RP <72 h ¹ <120 h ²	Whole blood/	= -5 C	= -5 C	= -20 C	3 yr
1 – EP Requirements, practice 2 – U.S. Requirements, practice					

Summary

- ZLB Source Plasma specifications are based on CFR and EP requirements.
- U.S. recovered plasma specifications are part of the short supply agreements between ZLB and blood centers.
- Both recovered and Source Plasma are suitable raw materials for fractionation.
- Storage conditions of -20°C are suitable for Source Plasma.
- Storage conditions of -18°C for 24 h and -5°C for 120 h are suitable for recovered plasma.
- Flash freezing does not add to quality and safety.